



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JAN 2 9 2009

Advanced Technology Laser, Co., Ltd. % Underwriters Laboratories, Inc. Mr. Morten Christensen 455 E. Trimble Road San Jose, California 95131-1230

Re: K083915

Trade/Device Name: Angelite Family of Intense Pulsed Light Systems

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery

and in dermatology

Regulatory Class: II Product Code: GEX Dated: January 16, 2009 Received: January 23, 2009

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

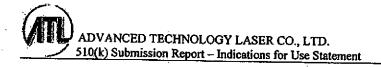
Mark of Miller

Mark N. Melkerson

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure



Section II Indications for Use Statement

510(k) Number:	
Device Name: Indications for Use:	Angelite Family of Intense Pulsed Light Systems
deliver pulsed-light energy) i	e Pulsed Light Systems (inclusive of the handpieces used to is indicated for use in surgical, aesthetic and cosmetic thermolysis, photocoagulation and dermatology) in the magnificant pigmented lesions and hair removal as follow:
Intense Pulse Light Energ treatment of inflammatory a	y Wavelengths from 400 - 950 nm are indicated for the acne.
scars and striae. For the tree wine stains, hemangiomas,	y Wavelengths from 560 - 1200 nm are indicated for the ented (epidermal and coetaneous) lesions including warts, atment of benign (cutaneous) vascular lesions including port facial, truncal and leg telangiectasias, rosacea, melasmna, ormas, poikiloderma of civatte, leg veins, facial veins and
3. Intense Pulse Light Energy treatment of unwanted hair	Wavelengths from 700 - 1200 nm are indicated for the (i.e., hair removal).
Prescription Use X (Part 21 CFR 801 Subpart D) (PLEASE DO NOT WRITE BEI	AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) LOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence	of CDRH, Office of Device Evaluation (ODE)
	(Division Sign-Off) Page 1 of 1
	Division of General, Restorative,
	and Neurological Devices
	510(k) Number 14085918